



ITW

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Carlos SCHULER, et al.) Atty. Docket No.: 0047.10
)
) Examiner: Unknown
)
Application No.: 10/601,127) Group Art Unit: 3761
)
Filed: 06/19/2003)
)
Title: SYSTEMS AND METHODS FOR)
AEROSOLIZING PHARMACEUTICAL)
FORMULATIONS)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, Virginia 22313-1450 on June 21, 2006

Signed: Minna Cotta

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56, §1.97 and §1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

The references listed in the attached Forms PTO/SB/08A and B may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

The references on the attached Form PTO/SB/08A and B were previously cited by or submitted to the PTO in a prior application relied upon for an earlier filing date. Accordingly, in compliance with 37 CFR §§1.98 (d), copies of these references have not been provided.

Attorney Docket No. 0047.10

This Information Disclosure Statement is being timely filed under 37 CFR §§1.97 and is being filed:

☒ within three months of the filing date of a national application or an RCE; within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or before the mailing date of a first Office action on the merits (whichever event occurs last);

☐ Please charge the amount of \$___ to Deposit Account 500348

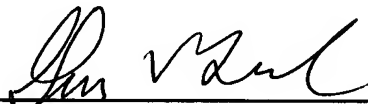
☒ If it is determined that any additional fees are due, the Commissioner is hereby authorized to charge such fees to Deposit Account 500348.

Respectfully submitted,

NEKTAR THERAPEUTICS

Dated: 21 JUN 2005

By:



Guy V. Tucker
Reg. No. 45,302

NEKTAR THERAPEUTICS
150 Industrial Road
San Carlos, CA 94070
(650) 631-3100



INFORMATION DISCLOSURE STATEMENT PTO-1449			ATTY. DOCKET NO. 0047.10		SERIAL NO. 10/601,127	
<u>Page 1 of 7</u>			APPLICANT Schuler, et al.			
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761	
U.S. PATENT DOCUMENTS						
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	2,587,215	02/1952	Priestly			
	3,788,310	01/1974	Fleischmann			
	3,837,341	09/1974	Bell			
	4,086,918	05/1978	Russo			
	4,106,503	08/1978	Rosenthal, et al.			
	4,114,608	09/1978	Russo			
	4,170,228	10/1979	Elson, et al.			
	4,259,951	04/1981	Chernack, et al.			
	4,274,404	06/1981	Molzan, et al.			
	4,284,083	08/1981	Lester			
	4,338,931	07/1982	Cavazza			
	4,391,283	07/1983	Sharpless, et al.			
	4,442,856	04/1984	Betz			
	4,444,202	04/1984	Rubin, et al.			
	4,484,577	11/1984	Sackner, et al.			
	4,495,944	01/1985	Brisson, et al.			
	4,533,137	08/1985	Sonne			
	4,558,710	12/1985	Eichler			
	4,592,348	06/1986	Waters, et al.			
	4,627,432	12/1986	Newell, et al.			
	4,677,975	07/1987	Edgar, et al.			
	4,778,054	10/1988	Newell, et al.			
	4,811,731	03/1989	Newell, et al.			
	4,907,583	03/1990	Wetterlin, et al.			
	4,926,852	05/1990	Zoltan, et al.			
	4,955,371	09/1990	Zamba, et al.			
	4,991,745	02/1991	Brown	222	212	
	5,027,806	07/1991	Zoltan, et al.			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 2 of 7</u>			ATTY. DOCKET NO. 0047.10		SERIAL NO. 10/601,127	
			APPLICANT Schuler, et al.			
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761	
U.S. PATENT DOCUMENTS						
	5,033,655	07/1991	Brown	222	212	
	5,040,527	08/1991	Larson, et al.			
	5,042,467	08/1991	Foley	128	200.23	
	5,042,472	08/1991	Bunin			
	5,069,204	12/1991	Smith, et al.			
	5,167,506	12/1992	Kilis, et al.			
	5,184,641	02/1993	Kuhn			
	5,201,308	04/1993	Newhouse			
	5,213,236	05/1993	Brown, et al.	222	185	
	5,284,133	02/1994	Burns, et al.			
	5,301,666	04/1994	Lerk, et al.			
	5,320,094	06/1994	Laube, et al.			
	5,333,106	07/1994	Lanpher, et al.			
	5,339,995	08/1994	Brown, et al.	222	185	
	5,364,838	11/1994	Rubsamen, et al.			
	5,377,877	01/1995	Brown, et al.	222	105	
	5,385,140	01/1995	Smith			
	5,408,994	04/1995	Wass, et al.			
	5,409,144	04/1995	Brown, et al.	222	185	
	5,419,315	05/1995	Rubsamen			
	5,435,301	07/1995	Herold			
	5,437,271	08/1995	Hodson, et al.			
	5,439,143	08/1995	Brown, et al.	222	185	
	5,447,150	09/1995	Bacon			
	5,447,151	09/1995	Bruna, et al.			
	5,458,135	10/1995	Patton, et al.	128	200.14	
	5,483,954	01/1996	Mecikalski			
	5,497,944	03/1996	Weston, et al.	128	200.14	
	5,509,404	04/1996	Lloyd, et al.			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 3 of 7</u>			ATTY. DOCKET NO. 0047.10		SERIAL NO. 10/601,127	
			APPLICANT Schuler, et al.			
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761	
U.S. PATENT DOCUMENTS						
	5,513,630	05/1996	Century			
	5,522,380	06/1996	Dwork	128	200.23	
	5,529,059	06/1996	Armstrong, et al.			
	5,533,505	07/1996	Kallstrand			
	5,542,412	08/1996	Century			
	5,558,085	09/1996	Rubsamen, et al.			
	5,568,807	10/1996	Mecikalski	128	203.21	
	5,586,550	12/1996	Ivri, et al.			
	5,617,845	04/1997	Poss, et al.			
	5,622,166	04/1997	Eisele, et al.	128	203.12	
	5,653,223	08/1997	Pruitt	128	200.21	
	5,654,007	08/1997	Johnson, et al.	424	489	
	5,655,520	08/1997	Howe, et al.	128	203.12	
	5,672,581	09/1997	Rubsamen			
	5,692,492	12/1997	Bruna, et al.			
	5,692,496	12/1997	Casper, et al.			
	5,692,498	12/1997	Lurie, et al.	128	205.24	
	5,699,789	12/1997	Hendricks			
	5,724,959	03/1998	McAughey, et al.			
	5,727,546	03/1998	Clarke, et al.			
	5,740,794	04/1998	Smith, et al.	128	203.15	
	5,752,505	05/1998	Ohki, et al.	128	203.15	
	5,775,320	07/1998	Patton, et al.	128	200.14	
	5,785,049	07/1998	Smith, et al.	128	203.15	
	5,813,401	09/1998	Radcliff, et al.			
	5,823,183	10/1998	Casper, et al.			
	5,826,571	10/1998	Casper, et al.			
	5,826,633	10/1998	Parks, et al.	141	489	
	5,855,202	01/1999	Andrade			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 4 of 7</u>			ATTY. DOCKET NO. 0047.10		SERIAL NO. 10/601,127	
			APPLICANT Schuler, et al.			
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761	
U.S. PATENT DOCUMENTS						
	5,873,358	02/1999	Gonda, et al.			
	5,875,776	03/1999	Vaghefi, et al.			
	5,881,719	03/1999	Gottenauer, et al.	128	203.15	
	5,884,620	03/1999	Gonda, et al.			
	5,896,853	04/1999	Howlett			
	5,901,703	05/1999	Ohki, et al.	128	200.14	
	5,921,237	07/1999	Eisele			
	5,922,354	07/1999	Johnson, et al.	424	489	
	5,941,240	08/1999	Gonda, et al.			
	5,975,076	11/1999	Yianneskis			
	5,983,893	11/1999	Wetterlin			
	5,988,163	11/1999	Casper			
	5,993,421	11/1999	Kriesel			
	6,006,747	12/1999	Eisele			
	6,012,454	01/2000	Hodson, et al.			
	6,029,661	02/2000	Whaley, et al.			
	6,029,663	02/2000	Eisele, et al.	128	203.21	
	6,055,979	05/2000	Fuchs			
	6,055,980	05/2000	Mecikalski			
	6,062,219	05/2000	Lurie, et al.			
	6,065,472	05/2000	Anderson, et al.	128	203.21	
	6,070,573	06/2000	Howe, et al			
	6,076,523	06/2000	Jones, et a.			
	6,085,753	07/2000	Gonda, et al.			
	6,089,228	07/2000	Smith, et al.	128	203.15	
	6,095,134	08/2000	Sievers, et al.			
	6,102,036	08/2000	Slutsky, et al.			
	6,105,574	08/2000	Jahnsson			
	6,109,261	08/2000	Clarke, et al.			
	6,116,237	09/2000	Schultz, et al.			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 5 of 7</u>			ATTY. DOCKET NO. 0047.10		SERIAL NO. 10/601,127		
			APPLICANT Schuler, et al.				
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761		
U.S. PATENT DOCUMENTS							
	6,116,238	09/2000	Jackson, et al.	128	203.15		
	6,116,239	09/2000	Volgyesi				
	6,138,673	10/2000	Shepard	128	203.15		
	6,142,146	11/2000	Abrams, et al.				
	6,161,524	11/1992	Evans				
	6,176,237	01/2001	Wunderlich, et al.	128	203.12		
FOREIGN PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 91/14422	10/1991	PCT/US			<input type="checkbox"/>	<input type="checkbox"/>
	WO 96/09085	03/1996	PCT/US			<input type="checkbox"/>	<input type="checkbox"/>
	WO 96/32149	10/1996	PCT/US			<input type="checkbox"/>	<input type="checkbox"/>
	WO 98/32479	07/1998	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	WO 99/46055	09/1999	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	WO 99/16419	09/1997	US			<input type="checkbox"/>	<input type="checkbox"/>
	WO 95/24183	02/1995	US			<input type="checkbox"/>	<input type="checkbox"/>
	WO 99/47196	03/1999	US			<input type="checkbox"/>	<input type="checkbox"/>
	WO 95/34337	12/1995	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	WO 97/40819	11/1997	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	WO 99/27987	06/1999	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	WO 96/30068	10/1996	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	WO 00/21594	04/2000	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	WO 00/01435	01/2000	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	EP 0808635A2	11/1997	Europe			<input type="checkbox"/>	<input type="checkbox"/>
	EP 0714314B1	10/1998	Europe			<input type="checkbox"/>	<input type="checkbox"/>

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 6 of 7</u>			ATTY. DOCKET NO. 0047.10		SERIAL NO. 10/601,127	
			APPLICANT Schuler, et al.			
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761	
FOREIGN PATENT DOCUMENTS						
	EP 0805696B1	03/2000	Europe			<input type="checkbox"/> <input type="checkbox"/>
	HU 212398	06/1996	Boehringer			<input type="checkbox"/> <input type="checkbox"/>
	HU 219215	03/2001	Merck			<input type="checkbox"/> <input type="checkbox"/>
	HU 214757	05/1998	Asta			<input type="checkbox"/> <input type="checkbox"/>
	1,598,053	09/1981	United Kingdom			<input type="checkbox"/> <input type="checkbox"/>
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
	Nantel, et al., "Flow Targeting System for DPI Clinical Trials," <i>Barrett Medical Aerosol Research Laboratory</i> , pp. 136.					
	Prime, D., et al. "The Flixotide Diskus a new multi powder inhaler-in-vitro evaluation using an inhalation simulator," <i>Glaxo Research and Development</i> , pp 138.					
	Prime, D., et al. "The Flixotide Diskus a new multi powder inhaler-consistency of dose and fine particle mass, protection from moisture," <i>Glaxo Research and Development</i> , pp 137.					
	Robertson, D.L.N., et al., "The influence of (pseudo) polymorphic forms of lactose on dry power inhaler performance," <i>School of Pharmacy and Pharmacology</i> , pp. 139					
	Barrowcliffe, et al., "The In-Vitro Evaluation of Novel Multi-Dose Dry Power Inhaler," <i>CCL Pharmaceuticals Ltd.</i> , pp. 82-85.					
	Malton, et al., "A Comparison of <i>in vitro</i> drug delivery from two multidose powder inhalation devices," <i>European Journal of Clinical Research</i> , 1995:7; pp. 177-193.					
	Agenda for <i>Asthma Therapy I – Thematic Poster Session May 12, 1996</i> , <i>American Journal of Respiratory Critical Care Medicine</i> , 153(4), April 1996.					
	Malton, et al., "A Comparison of <i>in vitro</i> drug delivery from salbutamol Diskus and terbutaline Turbuhaler inhalers," <i>J. Pharm. Med.</i> , (1996) 6, pp. 35-48.					
	Chrystyn, Henry, "The Diskus Inhaler- A Review of its Pharmaceutical and Clinical Performance," <i>Clin. Drug Invest.</i> , 18(4):pp. 287-296 (1999).					
	Newhouse, et al., "Clickhaler (a Novel Dry Powder Inhaler) Provides similar Bronchodilatation to Pressurized Metered-Dose Inhaler, Even at Low Flow Rates," <i>CHEST</i> 115(4):pp. 952-956: April 1999.					
	Clark, "Effect of powder inhaler resistance upon inspiratory profiles in health & disease," <i>Respirator Drug Delivery IV</i> , 1994.					
	Clark, "The relationship between powder inhaler resistance and peak inspiratory conditions in healthy volunteers – implications for <i>in vitro</i> testing," <i>Journal of Aerosol Science</i> , 1993.					
	"Characteristics of an active multiple dose dry powder inhaler," <i>Dura RDD</i> , 1994.					
	Dolovich, "Physical principles underlying aerosol therapy," <i>Journal of Aerosol Medicine</i> , 1989.					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 7 of 7</u>	ATTY. DOCKET NO. 0047.10	SERIAL NO. 10/601,127
	APPLICANT Schuler, et al.	
	FILING DATE June 19, 2003	GROUP ART UNIT: 3761
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	Elliott, et al., "Parental absorption of insulin from the lung in diabetic children," <i>Aust. Paediatric Journal</i> , 23, pp. 293-297 (1987).	
	Lawford, et al., "Pressurized Aerosol Inhaler Technique: How Important are Inhalation from Residual Volume, Inspiratory Flow Rate and the Time Interval Between Puffs?", <i>Br. J. Dist. Chest</i> , 77, pp. 276-281 (1983).	
	Ross, et al., "Effect of Inhalation Flow Rate on the Dosing Characteristics of Dry Powder Inhaler (DPI) and Metered Dose Inhaler (MDI) Products," <i>Journal of Aerosol Medicine</i> , Vol. 9, No. 2., pp. 215-226 (1996).	
	Hill, "Characteristics of an Active, Multiple Dose Dry Powder Inhaler," <i>Respiratory Drug Delivery IV</i> , pp. 109-116 (1994).	
	Conway, et al., "Comparison of peak Pressure Drops Through Powder Inhalers During Inspiration at Maximum Flow Rate" Abstract from <i>American Journal of Respiratory and Critical Care Medicine</i> , Vol. 153, No. 4, A59, (April 1996).	
EXAMINER		DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.